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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/945,655	10/24/97	LOFROTH	J 1103326-283

EXAMINER

HM12/0517

WEITMAN, E  
ART UNIT PAPER NUMBER

1617

DATE MAILED: 05/17/99

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

### OFFICE ACTION SUMMARY

Responsive to communication(s) filed on 3/2/99

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 1 - 13 is/are pending in the application.  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 Claim(s) \_\_\_\_\_ is/are allowed.  
 Claim(s) 1 - 13 is/are rejected.  
 Claim(s) \_\_\_\_\_ is/are objected to.  
 Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  
 The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.  
 The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.  
 The specification is objected to by the Examiner.  
 The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been received.  
 received.  
 received in Application No. (Series Code/Serial Number) \_\_\_\_\_  
 received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of Reference Cited, PTO-892  
 Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_  
 Interview Summary, PTO-413  
 Notice of Draftsperson's Patent Drawing Review, PTO-948  
 Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

Art Unit: 1615

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 5, 6, 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rencher.

Rencher teaches a pharmaceutical delivery vehicle comprising xanthan gum (abstract).  
Water insoluble materials to retard release are specified (column 3 lines 10-14). (Holesterol lowering agents are disclosed (column 3 line 43).

Applicants stipulate that fluvastatin is known in the art to reduce cholesterol levels (page 4 lines 19-25).

It would have been obvious to one of ordinary skill to deliver fluvastatin in the vehicle of Rencher in view of the fact that the drug is known in the art to reduce cholesterol.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amselem et al. or Sakamoto et al.

Art Unit: 1615

Anselem et al. and Sakamoto et al. teach a vehicle comprising a lipid and fat respectively for delivering water-soluble drugs (Abstract). Waxes and paraffin are specified (column 5 lines 31-34 and column 3 line 32 respectively). Applicants stipulate that fluvastatin is water soluble (page 5 line 7).

It would have been obvious to one of ordinary skill to deliver fluvastatin with the vehicle of Anselem et al. or Sakamoto et al. in view of the fact that fluvastatin is water soluble.

As to the claimed erosion, it is argued that the vehicle melts over time in the manner of a suppository at body temperature. As to the claimed paraffin, Anselem et al. teaches waxes solid at 25 C (column 5 lines 34-35). Paraffin is known to the layman as such a wax.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 7-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kotwal et al. or Eichel et al.

Kotwal et al. and Eichel et al. teach coated vehicles for controlled release of water soluble drugs (Abstracts). Both disclose ethyl cellulose as a coat for controlled release (column 2 line 40 and Abstract respectively).

Applicants stipulate soluble (see above).

Art Unit: 1615

It would have been obvious to deliver fluvastatin with the vehicle of Kotwal et al or Eichel et al. in view of the fact that Fluvastatin is water soluble.

Claims 8, 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 8 'Hydroxpropyl' is indefinite. In claim 12 'including' is non-limiting.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is (703) 308-4432. The examiner can normally be reached on M-F from 9:00 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T. K. Page, can be reached on (703) 308-2927. The fax phone number for this Group is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

E. Webman:jmr

Nov. 17, 1998

5/14/99

EDWARD J. WEBMAN  
PRIMARY EXAMINER  
GROUP 1500

IDS/1449 FILED 4/23/99 WILL BE ADDRESSED  
IN NEXT ACTION.